PATENT COOPERATION TREATY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

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Date of mailing *(day/month/year)* 11 February 2005 (11.02.2005)

Applicant's or agent's file reference

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/BR 2004/000224	12 November 2004 (12.11.2004)	13 November 2003 (13.11.2003)

International Patent Classification (IPC) or both national classification and IPC
A61K 35/78, 38/00, C12N 15/82

Applicant
UNIVERSIDADE FEDERAL DO RIO DE JANEIRO - UFRJ

1. This opinion contains indications relating to the following items:

- [x] Cont. No. I Basis of the opinion
- [ ] Cont. No. II Priority
- [ ] Cont. No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Cont. No. IV Lack of unity of invention
- [x] Cont. No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Cont. No. VI Certain documents cited
- [ ] Cont. No. VII Certain defects in the international application
- [ ] Cont. No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Continuation No. I

Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed.

Continuation No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims **1-30**	**YES**
	Claims **----**	**NO**
Inventive step (IS)	Claims **1-30**	**YES**
	Claims **----**	**NO**
Industrial applicability (IA)	Claims **1-30**	**YES**
	Claims **----**	**NO**

2. Citations and explanations:

US 5275819 A concerns a pulsating release composition comprising porous natural pollen grain microspheres loaded with a biologically active substance foreign to the naturally occurring pollen grain microspheres, these microspheres being coated with one or more barrier layers of sufficient resistance to dissolution in animal fluid to delay the release of the under lying body of active substance until after the pulse provided by the previously released substance has subsided. The active substances may be e.g. analgesics, antibacterials, antibiotics, anti-cariogenics, anti-inflammatories, anti-viral agents or hormones. The pulsating release system enables bioadhesion of the pollen grain based natural microsphere drug carriers to the mucosa.

Also WO 1992/019229 A1 concerns loaded pollen grains which are suitable for use as delivery systems for introducing biologically active substances into mammals. The most preferred pollen grains are those that have spiny or irregular or fragmented surfaces. Also disclosed are a method of pre-treating the pollen grains to remove antigenic materials, a method of loading the pollen grains with the biologically active material, and a method of incorporating such pre-treated, loaded pollen grains into pharmaceutical formulations.

Present claims concern pollen as carriers as well. However, the pharmaceutically active compounds are foreign polypeptides which are a result of the genetic modification of the plant which produces tissue or cells of the male vegetal reproductive system.

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WO 2002/099111 A2 suggests to use anthers for the expression of proteins. These proteins may be used as pharmaceutical agent. But according to this document male parts of the plants are not used as delivery system or as system to bring the drug to the mucosa and the e.g. pollen are not co-reactive substances. Thus, the subject-matters of the claims 1-30 are not obvious from the cited documents.

Industrial applicability is given for the subject-matters of all claims.